TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
2003-0312		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CU2004/000017	28.12.2004	30.12.2003

International Patent Classification (IPC) or national classification and IPC

A61K39/39 (2006.01)

Applicant

INSTITUTO FINLAY. CENTRO DE INVESTIGACIÓN-PRODUCCIÓN DE SUEROS Y VACUNAS

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of _____ sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____ , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/ES	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CU2004/000017

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* _____ received by this Authority on _____

nos.* _____ received by this Authority on _____

☐ the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CU2004/000017

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	4, 6, 10	YES
	Claims	1-3, 5, 7-9, 11-14	NO
Inventive step (IS)	Claims	4, 6, 10	YES
	Claims	1-3, 5, 7-9, 11-14	NO
Industrial applicability (IA)	Claims	1-14	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Documents taken into consideration:

D1: WO 03/094964 A 20.11.2003

D2: WO 02/072012 A 19.09.2002

The subject matter of the present invention relates to proteoliposomes for use as adjuvants for inducing CTL activity in vaccine compositions. The proteoliposomes according to the invention are of bacterial origin, and particularly from *Neisseria* (claims 1 to 4). The invention further relates to a vaccine composition including the proteoliposome and one or more antigens and carriers, wherein the antigen can be bound to the proteoliposome by inserting same into the lipid bilayer, by conjugation or by co-delivery of the antigen and the proteoliposome (claims 1 to 12); and the use of the vaccine composition for protecting mammals from and treating tumour diseases (claim 13). The invention further includes the immunisation schedule (claim 14).

Document D1 describes the use of proteoliposomes derived from outer membrane proteins of Gram-negative bacteria and particularly *Neisseria meningitidis* as adjuvants for

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

modifying the immune response to allergens towards a Th1 cellular response (page 8, line 20 to page 9, line 12). The bond between the allergen and the proteoliposome is achieved by covalent and non-covalent methods, and said allergens are included in the same concentrations relative to the proteoliposome as in the vaccine of the invention (page 10, lines 18-23). The immunisation schedule is the same as in the present application (page 9, lines 13-16).

It follows that claims 1 to 3, 5, 7, 8, 11 and 14 of the present application are not novel over the known prior art (PCT Article 33(2)).

Document D2 describes adjuvants for vaccines of which the main component is proteosomes from Gram-negative bacteria, including *Neisseria meningitidis*, inducing an antigen response and increasing the type 1 cellular response. The routes of administration are the same as in the present application (page 4, lines 10-18). The resulting vaccines can be used against viruses, parasites or certain bacterial pathogens, as well as against cancer and auto-immune diseases (page 5, lines 11-16).

It follows that the features in claims 9, 12 and 13 are already known from document D2 and these dependent claims accordingly lack novelty (PCT Article 33(2)).

Claims 1 to 14 are industrially applicable (PCT Article 33(4)).